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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,713	07/07/2003	Rolland F. Hebert		7933

29133 7590 12/17/2003

ROLLAND HEBERT
427 BELLEVUE AVE E. SUITE 301
SEATTLE, WA 98102

EXAMINER	
KHARE, DEVESH	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,713	HEBERT, ROLLAND F.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-5 are currently pending in this application.

35 U.S.C. 112, second paragraph rejection

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2, the phrase "a disease or a condition" is not defined, rendering the claim indefinite. The phrase "a disease or a condition" is ambiguous in absence of a specific disease or condition, and renders claims 1 and 2 indefinite.

35 U.S.C. 112, first paragraph rejection

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2,4 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment for a disease by inhibition of ornithine decarboxylate, does not reasonably provide enablement for preventing a disease caused by inhibition of ornithine decarboxylate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable the invention commensurate in scope with these claims to prevent cancer, HIV, prozoal infections, acitinic keratosis, and hirsutism.

The factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art.

1. QUANTITY OF EXPERIMENTATION

With regard to factor one the quantity of experimentation needed, to determine the specific identity of the administration of a pharmaceutically effective amount of a compound applicant intends to utilize a method for prevention of a disease or a condition and preventing cancer, HIV, prozoal infections, acitinic keratosis, and hair growth including hirsutism by inhibition of ornithine decarboxylate, would require undue experimentation. At the very least, experimentation correlative to establishing the broad spectrum of efficacy should be provided. The absence of specific disclosures or the correlation of data to support applicant's assertions, invites the skilled artisan to engage in undue experimentation. The quantity of experimentation needed to determine the specific identity and combinations of the amounts of compounds needed to practice the instant methods as they relate to treating a patient in need of the asserted therapy and

preventing reoccurrence of condition treated or when a healthy person is administered the active agent and the prevention of conditions cited supra, would require a great deal of experimentation which would impose an undue burden upon the skilled artisan in this field. Additionally a time table for administration to achieve efficacious correlative therapy would be unduly burdensome to obtain in view of the guidance currently provided, although applicant alleges that their invention is enabled for the experimentation to administer a salt of 2-difluoromethyl-2,5-diaminopentanoic acid (DFMO) with chitosan, the instant disclosure appears to be limited to the administration of a salt of 2-difluoromethyl-2,5-diaminopentanoic acid (DFMO) with chitosan in methods for treating a disease or a condition only.

2. GUIDANCE PROVIDED

There is little guidance given in the specification as to the specific use of a composition for prevention of a disease or a condition and preventing hair growth by inhibition of ornithine decarboxylate. There is not seen guidance as to how the skilled artisan can establish a sufficient time table or establish a prevention regiment in healthy subjects or newborns to eradicate/prevent the conditions asserted in the methods of the instant disclosure. There has not been provided a clear reference to prior art disclosures which give guidance as to how the skilled artisans in this art would prevent diseases by inhibition of ornithine decarboxylate.

3. WORKING EXAMPLES IN SPECIFICATION

The examples of the efficacy of the instant methods and the applicability of the active agents are set forth in the following example:

Example 1, is drawn to the effect of a cream containing 20% DFMO with chitosan to healthy individuals in an outpatient clinic.

The EXAMPLE advanced in the instant specification is not seen as sufficient to support the breadth of the claims for prevention of a disease or a condition and preventing hair growth by inhibition of ornithine decarboxylate.

4. NATURE OF THE INVENTION

It is known in this art that certain ornithine decarboxylate inhibitors have efficacy in altering the character of human hair growth and treatment of female hirsutism (U.S. Patent 4,720,489, see claim 1 and col. 2, lines 1-2), treating the skin cancer and as a preventative to skin exposed to actinic radiation (U.S. Patent 5,851,537, abstract and col. 3, lines 7-22) and for the treatment or prophylaxis of cancer (U.S. Patent 6,277,411, col. 4, lines 44-47).

5. STATE OF THE PRIOR ART

The instant claimed methods are drawn for the treatment of a disease or a condition by inhibition of ornithine decarboxylase. The following patents are cited to show the state of the prior art:

Alberts et al. U.S. 5,851,537, Dec. 22, 1998.

Shander U.S. 4,720,489, Jan. 19, 1988.

Shaked et al. U.S. 6,277,411, Aug. 21, 2001.

6. THE PREDICTABILITY OF THE ART

To extrapolate the data from a composition containing DFMO and chitosan for the combined treatment and prevention of a disease or a condition and prevention of cancer, HIV, prozoal infections, acitinic keratosis, and hair growth including hirsutism is not seen to be disclosed in the prior art. Neither the specification nor the prior art provides adequate guidance for preventing a disease or a condition by inhibition of ornithine decarboxylate. To extrapolate the scant data and guidance provided to preventive therapy would be to ignore the high degree of unpredictability in preventive treatments and therapies.

7. BREATH OF THE CLAIMS

Claims 1 and 3 are drawn to a method of treatment of a disease or a condition by inhibition of ornithine decarboxylase wherein the disease or a condition is selected from the group consisting of cancer, benign prostatic hypertrophy and hirsutism. Claims 2 and 4 are drawn to a method of prevention of a disease or a condition by inhibition of ornithine decarboxylase wherein the disease or a condition is selected from the group consisting of cancer, HIV, prozoal infections, acitinic keratosis, and hirsutism. Claim 5 is also drawn to the prevention of hair growth with the composition of DFMO and chitosan.

8. THE RELATIVE SKILL IN THE ART

The relative skill in the art as it relates to the combined treatment and prevention of a disease or a condition and prevention of hair growth with a composition containing DFMO and chitosan, is that of a Ph.D. or M.D. level.

Presently, the instant specification is not seen to provide an enabling disclosure for the scope of the invention as set forth in claims which encompass the prevention of a disease or a condition and prevention of hair growth. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use

applicant's alleged discovery, not how to find out how to use it for themselves, see In re Gardner et al. 166 USPQ 138 (CCPA 1970). In the instant case, the amount of experimentation needed to verify the efficacy of a composition containing DFMO and chitosan which prevents a disease or a condition by inhibition of ornithine decarboxylase, would indeed be voluminous and unduly burdensome in view of the teachings of the instant disclosure.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaked et al. (Shaked) (U.S. Patent 6,277,411) in view of Shander (U.S. Patent 4,720,489). Claims 1 and 3 are drawn to a method for the treatment of a disease or a condition, which is treatable, by inhibition of ornithine decarboxylase, which comprises administration of a salt of DFMO with chitosan. Additional claim limitations include a disease or condition selected from the group consisting of cancer, benign prostatic hypertrophy, protozoal infections, actinic keratosis, and hirsutism.

Shaked teaches a pharmaceutical formulation containing DFMO for the treatment of cancer (see abstract). Shaked discloses that a DFMO containing pharmaceutical formulation may be modified for treating specific cancers (col. 1, lines 15-20). Shaked also discloses that the said formulation can be employed for the treatment or prophylaxis of cancer (col. 4, lines 44-47). Shaked discloses the said formulation

comprising DFMO and a polymer such as cihitosan (col. 12, lines 14-19). While the Shaked's DFMO containing pharmaceutical formulation is closely analogous to the applicant's formulation and methods of use, Shaked does not disclose the use of a formulation of DFMO to treat hirsutism.

Shander teaches the applications in the treatment of female hirsutism (col. 2, lines 1-2). Shander discloses the topical application of ornithine decarboxylase inhibitors in altering the rate and character of hair growth (col. 3, lines 27-29). Shander discloses Shander discloses the inhibition of androgen mediated hair growth in male hamsters following the topical application of DFMO (col. 4, lines 17-21). It is noted that the Shander's method does not use chitosan with DFMO (claims 1-7).

It would have been obvious to person having ordinary skill in the art at the time the invention was made, to select the formulation containing a salt of DFMO and chitosan from among those taught by prior arts of Shaked and Shander in the treatment or prevention of cancer and hair growth because Sheked had disclosed that DFMO containing oral pharmaceutical formulations have a varied release profile for the treatment of cancer (see col. 1, lines 18-20).

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (703)605-

1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be

reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
December 4, 2003